State of California—Health and Human Services Agency
Department of Health Services

SANDRA SHEWRY
Director

ARNOLD SCHWARZENEGGER
Governor

April 22, 2004

Dear Interested Parties:

MEDI-CAL CLINICAL LABORATORY SERVICES REQUEST FOR APPLICATION (RFA) 04-35199 ADMINISTRATIVE BULLETIN 3, ADDENDUM 2

Administrative Bulletin 3, Addendum 2, issued by the California Department of Health Services, Office of Medi-Cal Procurement (OMCP), announces revised text and modified replacement forms for Medi-Cal Clinical Laboratory Services (RFA 04-35199). Please replace the existing pages in the RFA with the new pages provided in this addendum using the guide that follows:

Remove (existing pages)	**Replace** (new pages)
Pages 25-26	Pages 25-26
Attachment 3, page 1 of 2	Attachment 3, page 1 of 2
Attachment 8	Attachment 8
Exhibit A, Attachment 2, Question 3	Exhibit A, Attachment 2, Question 3

Within the text of the document, changes appear in underlined print with a vertical bar appearing to the right of the paragraph where changes were made.

If you have already submitted a Mandatory Non-binding Letter of Intent (Attachment 8) on the original form in the RFA, you will be contacted by phone to obtain your provider number for the form. If you have not already submitted a Mandatory Non-binding Letter of Intent (Attachment 8), and intend to submit one before the April 30, 2004 deadline, please use the replacement form included in this addendum for your submission.

The entire RFA, including all administrative bulletins and addenda, is available for electronic download at OMCP's website located at www.dhs.ca.gov/omcp by using the "Medi-Cal Clinical Laboratory Services" link on the homepage. For your convenience in filling out the application and to assist you in the electronic submission (CD-ROM) of your application, all attachments and exhibits that require entries have been modified to allow completion (fill-in) directly onto the electronic version of the document. You will need to download the attachments and exhibits from the website referenced above

which are available on the download page for this procurement. Please be advised that DHS will construe any alterations, modifications, additions or deletions to the printed verbiage on any RFA exhibit, attachment, form, etc. to be a "counter proposal", and will deem your application as non-responsive and rejected from further consideration.

If you should have further questions, please contact Jesse Tanguileg, lead analyst assigned to this procurement, at (916) 255-6032.

Sincerely,

Donna Martinez, Chief
Office of Medi-Cal Procurement

L. Application Questions

1. Fiscal and Management Anti-Fraud Activities Section

Activity 1 **1. To what extent does the Applicant's response ensure that clinical laboratory tests ordered by licensed practitioners are monitored in a manner that detects potential ordering abuses?**	**Points Awarded (0-4)**
1.1 To what extent does the mechanism described ensure that Activity 1 will be accomplished?	
1.2 To what extent do the key indicators presented ensure that Activity 1 will be accomplished?	
1.3 To what extent does the frequency of data collection and data analysis described ensure that Activity 1 will be accomplished?	

Activity 2 **2. To what extent does the Applicant's response ensure that the selection of CPT codes used to bill accurately describes the clinical laboratory tests or examinations that were ordered and performed.?**	**Points Awarded (0-4)**
2.1 To what extent does the mechanism described ensure that Activity 2 will be accomplished?	
2.2 To what extent do the key indicators presented ensure that Activity 2 will be accomplished?	
2.3 To what extent does the frequency of data collection and data analysis described ensure that Activity 2 will be accomplished?	
Activity 3 **3. To what extent does the Applicant's response ensure that Organ and Disease Oriented Panel codes, as defined in the CPT, are billed only if all defined components of the panel are performed?**	**Points Awarded (0-4)**
3.1 To what extent does the mechanism described ensure that Activity 3 will be accomplished?	
3.2 To what extent do the key indicators presented ensure that Activity 3 will be accomplished?	
3.3 To what extent does the frequency of data collection and data analysis described ensure that Activity 3 will be accomplished?	

Activity 4 **4. To what extent does the Applicant's response ensure that the clinical laboratory performs only those clinical laboratory tests or examinations ordered by the licensed practitioner and, for any subsequent additional (add-on) clinical laboratory tests or examinations, ensure that the clinical laboratory obtains written orders within thirty (30) calendar days?**	**Points Awarded (0-4)**
4.1 To what extent does the mechanism described ensure that Activity 4 will be accomplished?	
4.2 To what extent do the key indicators presented ensure that Activity 4 will be accomplished?	
4.3 To what extent does the frequency of data collection and data analysis described ensure that Activity 4 will be accomplished?	

Activity 5 **5. To what extent does the Applicant's response ensure that the clinical laboratory, prior to billing, verifies with the licensed practitioner the actual clinical laboratory test or examination that the licensed practitioner wants performed when a specimen is received without a valid test order or with an ambiguous test order?**	**Points Awarded (0-4)**
5.1 To what extent does the mechanism described ensure that Activity 5 will be accomplished?	
5.2 To what extent do the key indicators presented ensure that Activity 5 will be accomplished?	
5.3 To what extent does the frequency of data collection and data analysis described ensure that Activity 5 will be accomplished?	
Activity 6 **6. To what extent does the Applicant's response ensure that individuals with technical expertise in clinical laboratory testing or examination, review claims prior to billing for appropriateness of coding?**	**Points Awarded (0-4)**

REQUIRED FORMS AND LICENSES

Qualification Requirements. I certify that the clinical laboratory submitted the following items: (If No, please explain on Attachment 5.)		**Confirmed by DHS**
☐ Yes ☐ No	**1.** A copy of the CLIA Laboratory Personnel Report – Form HCFA 209 (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	**2.** A copy of the State of California Laboratory Personnel Report – form LAB 116A (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	**3.** The name, business address and telephone number of the person(s) or entity responsible for billing during the calendar year of 2003, and provide copies of contractual agreements, if any. (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	**4.** The name, business address and telephone number of the person(s) or entity responsible for obtaining new clients for the clinical laboratory and provide copies of contractual agreements, if any. (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	**5.** A list of all licensed practitioners who perform the professional component of clinical laboratory tests or examinations for the clinical laboratory separately identifying those licensed practitioners who independently bill for the professional component of clinical laboratory tests or examinations utilizing the CLIA certificate of the Applicant. (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	**6.** A copy of the business name, address and CLIA number of any other clinical laboratory where the Contractor's laboratory director also serves as a laboratory director. (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	**7.** A copy of the laboratory director's current medical license or license as a bioanalyst or director pursuant to Division 2, Chapter 3, Business and Professions Code. (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	**8.** A copy of the contractual agreement between the clinical laboratory and laboratory director. (Project Personnel Section)	☐ Yes ☐ No
☐ Yes ☐ No	**9.** A copy of the local business license. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No
☐ Yes ☐ No	**10.** A copy of the California Clinical Laboratory License. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No
☐ Yes ☐ No	**11.** A copy of the lease agreement for the clinical laboratory's business address. If there is no agreement, submit the name, address and telephone number of the property owner. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No
☐ Yes ☐ No	**12.** A copy of the HIV testing authorization from the State of California, if HIV tests are performed. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No
☐ Yes ☐ No	**13.** A copy of the proficiency test score results for all regulated analytes for the calendar years 2002 and 2003. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No
☐ Yes ☐ No	**14.** A listing of all current third party payors as defined in the Glossary of Terms (See Appendix 1) and a copy of the first page of the latest remittance advice statement received by the clinical laboratory from each third party payor. (Facilities, Resources and Equipment Section)	☐ Yes ☐ No

Mandatory Letter of Intent

Purpose	The purpose of this non-binding Mandatory Letter of Intent is to assist DHS in determining the staffing needs for the Application evaluation process and to improve future procurements.
Information requested	DHS is interested in knowing if the clinical laboratory intends to submit an Application or the reasons for not submitting an Application. Completion of this form is **mandatory**. **If this Mandatory Letter of Intent is not submitted, participation in the Medi-Cal program as a provider will be terminated and the provider number deactivated upon contract commencement.**
Action to take	Indicate the intention to submit an Application by checking item 1 or 2 below. Follow the instructions below the selection.

1. ☐ The clinical laboratory intends to submit an Application.

A. Check box number 1 if the above statement reflects the intention of the clinical laboratory.

B. Complete the bottom portion of this form and return it to DHS as instructed in the RFA Section F entitled, "Mandatory Letter of Intent".

C. Submit a copy of the current CLIA certificate for the clinical laboratory.

D. Submit a copy of the current specialty / subspecialty certificate(s) for the clinical laboratory.

2. ☐ The clinical laboratory does not intend to submit an Application for this project.

A. Check box number 2 if the statement in item 2 reflects the intention of the clinical laboratory.

B. Indicate the reason(s) for not submitting an Application by checking any of the following statements that may apply.

☐ The clinical laboratory does not have the appropriate CLIA.

☐ The clinical laboratory lacks sufficient staff expertise or personnel resources to meet the requirements.

☐ The clinical laboratory lacks sufficient experience (i.e., not enough or wrong type).

☐ The clinical laboratory believes the qualification requirements are too restrictive.

☐ Not enough time was allowed for Application preparation.

☐ Too much paperwork is required to prepare an Application response.

☐ Other commitments and projects have a greater priority.

☐ The clinical laboratory did not learn about the contract opportunity soon enough.

☐ The clinical laboratory does not provide the services that DHS is seeking.

☐ Other reason:

Complete the bottom portion of this form and return it to DHS as instructed in the RFA Section F entitled, "Mandatory Letter of Intent".

Person authorized to bind this clinical laboratory as the sole proprietor, partner, corporate officer, or government official in matters regarding this application or the resulting contract:

Name of Clinical Lab:	Medi-Cal Provider Number:
Printed Name *(First, Last)*:	Title:
Telephone number: ( )	Fax number: ( )
Signature of Authorized Representative (sign in blue ink)	Date:

3. The clinical laboratory shall develop policies to ensure it does not employ, contract or submit claims for providers (1) who are listed in 42 U.S.C. 1320a-7 or (2) who have been convicted of a criminal offense related to health care or (3) who are suspended, excluded, or otherwise ineligible because of a sanction to receive, directly or indirectly, reimbursement from the Medi-Cal program and the provider or entity is listed on either the Suspended or Ineligible Provider List, published by DHS, to identify suspended and otherwise ineligible providers, or (4) is a person or entity listed on any list published by the federal DHHS Office of the Inspector General regarding the suspension or exclusion of individuals or entities from the federal Medicare and Medicaid programs, to identify suspended, excluded, or otherwise ineligible providers (refer to Exhibit A Scope of Work subsection 6(b)(iii).